REMARKS

Status of the Claims and Amendment

Claims 21, 33, 37, 38, 43, and 45 have been amended. Claims 22, 25-32, 34-36 and 40-42 are canceled herewith without prejudice or disclaimer. Claims 1-20 and 23-24 were previously canceled. Claims 21, 22, 33, 37-39, and 43-47 are all the pending claims in the present application.

Claims 21 and 45 have been amended to recite that the method is for accelerating differentiation and/or proliferation of a cerebral nerve stem cell or a cerebral nerve precursor cell comprising administering (2R)-2-propyloctanoic acid. Claims 37, 38, and 43 have been amended to recite "the cerebral nerve stem cells" and "the cerebral nerve precursor cell" to be commensurate with the amendments to claim 21. Claim 37 has also been amended to be dependent on claim 21. Claim 33 has been amended to recite a "cerebral nerve tissue or a cerebral neural function". Support for the amendments to claims 21, 33, 37, 38, 43, and 45 may be found throughout the specification as filed, and at, for example, page 3, line 10 to page 4, line 6, page 9, line 25 to page 10, line 11, and Examples 1-3.

Claims 46 and 47 are newly added. Support for new claim 46 may be found throughout the specification as filed, and at, for example, Example 3 on page 44, line 15 through page 46, line 13. Support for new claim 47 may be found throughout the specification as filed, and at, for example, page 5, line 5.

No new matter is added.

Claim of Priority

The Examiner is respectfully requested to acknowledge Applicants' claim of foreign priority to JP 2003-345123 filed October 3, 2003 and JP 2004-162909 filed June 1, 2004, as well as receipt of the certified copies of the priority documents, in the next Office Communication.

Information Disclosure Statement

Applicants thank the Examiner for consideration of the Information Disclosure Statements (IDS) filed on April 3, 2006, and January 2, 2009, by returning signed and initialed copies of PTO Forms SB/08 submitted therewith.

Election/Restrictions

Applicants thank the Examiner for acknowledgement of the Response filed July 22, 2009. In this respect, the Examiner appears to have withdrawn claims 22, 25, 35 and 36 insofar as they are directed to a non-elected invention or non-elected species.

Response to Rejections under 35 U.S.C. § 112

1. Claims 21 and 26-31 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. While the Examiner admits that the specification enables accelerating nerve regeneration in a mammal with (2R)-2-propyloctanoic acid, the Examiner asserts that the specification does not enable use of any fatty acid compound and its prodrug thereof.

The Examiner asserts that the state of the art regarding effectively regenerating nerves with any fatty acid compound was poorly developed and that the predictability of accelerating nerve regeneration in a mammal with any fatty acid compound and its prodrug is relatively low, although the relative skill in the art is fairly high.

With respect to the recited prodrug, the Examiner asserts that any guidance in the specification as to how to accelerate nerve regeneration with the recited prodrug is completely lacking. Specifically, the Examiner states that although the specification defines prodrugs of formula I to be either a hydrate or a non-hydrate (page 17, lines 12-14), there is no description or example of any prodrugs of formula I, or its effective activity.

Moreover, the Examiner cites Laeng et al. (WO 02/102989 A2; "Laeng") and states that the reference teaches that valproate, but not all fatty acids and their prodrugs can promote new growth.

The Examiner concludes that Applicants fail to provide sufficient information to practice the claimed invention, absent undue experimentation.

Applicants disagree for the reasons provided below, and assert that the Examiner's rejection is not properly supported by sound technical and scientific reasoning or evidentiary support in the record.

With respect to the recited fatty acid compound, the specification provides working examples of fatty acids such as (2R)-2-propyloctanoic acid. Moreover, based upon the technical knowledge available in the art at the time the invention was made, one of ordinary skill in the art would understand and be enabled to use fatty acids to accelerate nerve regeneration. For example, and contrary to the Examiner's understanding, the Laeng reference cited by the Examiner teaches that the lack of nerve growth promotion is from the addition of ***non-fatty acid*** compounds and compositions such as brain-derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3), retinoic acid (RA) and neuronal conditioned medium (NCM). In fact, the addition of a fatty acid, valproate, resulted in the promotion of nerve growth.

With respect to the recited prodrug, Applicants note that one of ordinary skill in the art would understand from reading the specification, for instance, at page 16, line 7-page 17, line 14 of the specification, how to prepare the claimed fatty acid prodrugs and that because the prodrug is converted to the claimed fatty acid compound, the effective activity of the recited prodrugs would be the same as that of its fatty acid. Further, the use of prodrugs is well-known in the pharmaceutical arts so that one of ordinary skill in the art would understand how to make prodrugs of the claimed fatty acids for use in accelerating nerve regeneration.

Accordingly, based upon the guidance available in the specification and the technical knowledge available at the time the invention was made, one of ordinary skill in the art would have been enabled to use the claimed method for accelerating nerve regeneration by administering a fatty acid compound or a salt or prodrug thereof with a reasonable expectation of success. Nevertheless, and solely to advance prosecution of the present application, claims 21 and 45 have been amended to further clarify that the claimed method is for accelerating differentiation and/or proliferation of a cerebral nerve stem cell or a cerebral nerve precursor cell in a mammal comprising administering an effective amount of (2R)-2-propyloctanoic acid or a salt thereof.

For the at least the same reasons discussed above, new claims 46 and 47 are enabled based upon the guidance in the specification and the knowledge available in the art.

Claims 25-32, 34-36 and 40-42 are canceled. Accordingly, the rejection with respect to claims 25-32, 34-36 and 40-42 is rendered moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

2. Claims 21 and 40-42 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for the regeneration of any nerve.

The Examiner's position appears to be based upon the same reasons set forth above. Additionally, the Examiner asserts that while the specification teaches that (2R)-2-propyloctanoic acid regenerates brain nerve cells, there are no further tests with a subset of fatty acids that effectively regenerate other types of nerve cells such as peripheral, spinal or optic nerves. *See* Page 36, lines 1-15. The Examiner concludes that the skilled artisan would have to undergo exhaustive studies to evaluate each compound and type of nerve cell, in order to be able to fully carry out the invention commensurate in scope with the claims

Applicants disagree for the same reasons discussed above. Nevertheless, and solely to advance prosecution of the present application, claim 21 has been amended to further clarify that the claimed method is for accelerating differentiation and/or proliferation of a cerebral nerve stem cell or a cerebral nerve precursor cell in a mammal comprising administering an effective amount of (2R)-2-propyloctanoic acid or a salt thereof. New claims 46 and 47 are enabled based upon the guidance in the specification and the knowledge available in the art.

Claims 40-42 are canceled. Accordingly, the rejection with respect to claims 40-42 is rendered moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Response to Claim rejections under 35 U.S.C. § 102

Claims 21, 26-34, 37-41, 44 and 45 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Ohuchida et al. (US 6,201,021 B1).

The Examiner asserts that Ohuchida teaches pentanoic acid derivatives, such as 2-propyloctanoic acid for treatment of neurodegenerative diseases and neuronal dysfunction caused by stroke or traumatic injury. The Examiner asserts that the pentanoic acid derivatives of Ohuchida elicit i) potent effects in improving astrocyte functions, ii) marked regeneration effects of GABA receptor responses against reactive astrocytes in which the compounds were effective in transforming reactive astrocytes to astrocytes and iii) suppressive effects on cell death in symbiotic neurons astrocytes in which dendrite generation in the neurons were detected.

Applicants respectfully disagree and assert that pursuant to M.P.E.P. § 2131, the reference must teach each and every element set forth in the claim to anticipate. Ohuchida does not expressly or inherently disclose the presently claimed method of claim 21 (from which claims 33, 37-39, 43 and 44 are dependent) and claim 45, for accelerating differentiation and/or proliferation of a cerebral nerve stem cell or a cerebral nerve precursor cell in a mammal comprising administering an effective amount of (2R)-2-propyloctanoic acid or a salt thereof.

Specifically, Ohuchida does not disclose disclose stem cells or nerve precursor cells. Ohuchida discloses reactive astrocytes which are already nerve cells and not precursor cells so that the reactive astrocytes of Ohuchida cannot be differentiated or proliferated. Further, as discussed at page 2, lines 23-24 of the specification, Ohuchida is the corresponding U.S. Patent of EP 0632088A which does not disclose a nerve stem cell or a nerve precursor cell for differentiation and/or proliferation.

For the at least the same reasons discussed above, Ohuchida does not anticipate new claims 46 and 47.

Claims 26-32, 34, and 40-42 are canceled. Accordingly, the rejection with respect to claims 26-32, 34, and 40-42 is rendered moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Response to Claim rejections under 35 U.S.C. § 103

Claim 43 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ohuchida in view of Mazo (Pittsburgh Post Gazette, April 12, 2000, pages 1-3).

The Examiner relies on Ohuchida as set forth above. The Examiner, however, admits that Ohuchida does not disclose transplanting nerve cells and relies on Mazo for the teaching of transplanting brain nerve cells.

Initially, Applicants note that claim 43 depends from independent claim 21, which is not rejected. Pursuant to M.P.E.P. § 2143.03, the present rejection is improper because if an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Thus, the obviousness rejection is moot based upon these grounds alone.

Nevertheless, as discussed above, Ohuchida is a deficient reference because Ohuchida does not disclose disclose stem cells or nerve precursor cells. Ohuchida discloses reactive astrocytes which are already nerve cells and not precursor cells so that the reactive astrocytes of Ohuchida cannot be differentiated or proliferated. Also, as acknowledged by the Examiner, Ohuchida does not does not disclose transplanting nerve cells. The Examiner's reliance on Mazo for allegedly teaching transplanting brain nerve cells does not cure the apparent deficiencies of Ohuchida. Further, in this respect, Mazo is directed to treatment of stroke. There is no description or indication at all in Mazo of what is useful for culture of an appropriate nerve stem cell for transplant or an appropriate nerve precursor cell for transplant. Accordingly, Mazo is not an appropriate publication sufficient to establish or support an obviousness rejection. In contrast,

claim 43 of the present invention is directed to a method which is useful for culture of a nerve stem cell for transplant or a nerve precursor cell for transplant.

Thus, neither Ohuchida nor Mazo, separately or combined, teach or suggest the presently claimed method of claim 21 (from which claim 43 is dependent) for accelerating differentiation and/or proliferation of a cerebral nerve stem cell or a cerebral nerve precursor cell in a mammal comprising administering an effective amount of (2R)-2-propyloctanoic acid or a salt thereof, much more a method which is useful for culture of a nerve stem cell for transplant or a nerve precursor cell for transplant.

For at least the same reasons discussed above, new claims 46 and 47 are not obvious in view of Ohuchida and Mazo.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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